

NHLBI Big Data Heart Failure Analysis Challenge

Instructions for Streamlined Approval of NHLBI Data Access Request (DAR)

February 28, 2020

Overview

For a general overview of the dbGaP Data Access Request and approval process, please watch [this video](#) (it is very helpful).

After viewing the video and reading this document, if you have any questions please contact nhlbi_challenge@nhlbi.nih.gov.

In short:

1. You complete an online application on the dbGaP web site (<https://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?page=login>).
2. Your Institutional Signing Official (SO) signs the application and submits to dbGaP
3. You will receive email notifying you about interim steps in the process
4. The request is reviewed by the NHLBI Data Access Committee (DAC), which will be prepared to consider requests for data-access using the generic template provided.
5. Both the requesting PI and SO will be notified by email of approval or disapproval.

Separate access requests must be filed by each institution represented in the Challenge team. Multiple data sets may be requested simultaneously using one “project”. Additional data set requests may be made at a later time using the same project. **Note: streamlined approvals will only apply for the NHLBI datasets included in the request.** The application must be updated if there are any changes in status, such as moving to another institution, adding or removing Internal Collaborators, and/or IRB approval status.

Pre-requisites for submitting a data access request:

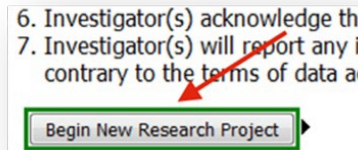
1. The applicant should be a senior investigator (tenure/tenure-track/or equivalent) who will be responsible for proper use of the data by others at the same institution with whom the data will be shared.
2. The applicant must have an [eRA Commons account](#)
3. The applicant must have a dbGaP account in good standing; a dbGaP account is automatically created once you log in with your eRA Commons ID.

Application Instructions for Streamlined Challenge Prize DAR approval

- Go to [dbGaP home page](#)
- Click on “Controlled Access Data” Log in with your eRA commons ID
- Under “My Projects” tab, click on “Create New Research Project



- Click “Begin New Research Project” (bottom of page)



“Choose Datasets” tab

In the “Choose Datasets” tab, you will see a long list of consent groups with check boxes next to them. Search for a “phs” accession number from the dataset you are requesting. The [NHLBI Big Data Analysis Heart Failure Challenge Data Collection](#) contains a collection of NHLBI datasets not requiring IRB approval and having consents which fall within the scope of the challenge. You may also add any other dbGaP datasets to your request. Some of these datasets may require additional documentation, such as IRB review of your project plan. Some accessions have multiple consent groups, each with a separate box to check. When you have clicked all of the appropriate boxes, go to the bottom of the page and click the “Add Selected and Continue” button. This will take you to the “Research Project” tab. You will have the opportunity to add more datasets later in the application process.

“Research Projects” tab

- “Descriptive Title of Project” – Please use exactly this title in the box:

“NHLBI Big Data Heart Failure Analysis Challenge”

- “Type of Research” – If you see this section (you may not), check “Other” and then add this text to the box:

“NHLBI Data Analysis Challenge Dataset Application”

- “Research Use Statement” – please add the **generic Research Use Statement** in Appendix 1, exactly as given:

“Phenotypic and genomic data from the selected studies will be used to develop a Solution(s) to the NHLBI Big Data Analysis Challenge: Creating New Paradigms for Heart Failure. The Solution(s) will consist of novel, open-source disease models that define sub-phenotypes of adult heart failure.

The requested data will not be used to investigate individual identity. Consent type and other Data Use Limitations (DUL) for each study will be respected in all analyses. Data from an individual with disease-specific consent will not be used in analyses outside of that restriction, including indirect uses. For example, an individual with consent restricted to lung function studies will not be used to develop a Solution. We intend to publish or otherwise broadly share any findings from these analyses with the scientific community.

The requested NHLBI-funded data may be combined with data from the same or other studies (obtained from dbGaP or other sources), to improve the power for novel discoveries, while respecting Data Use Limitations and the consent of all participants. We expect that this activity creates no additional risks to participants..”

Please enter your RUS in the area below. The RUS should be one or two paragraphs in length and include research objectives, the study design, and an analysis plan (including the phenotypic characteristics that will be tested for association with genetic variants). If you are requesting multiple datasets, please describe how you will use them. Examples of RUS can be found at [GDS website](#). Please limit your RUS to 2200 characters.

☒ I am requesting permission to use cloud computing to carry out the research as described

- If using a cloud environment to develop your Solution, check the box under the Research Statement labeled “I am requesting permission to use cloud computing...” This will cause a “Cloud Use Statement” box to appear. Enter your statement.

Cloud Use Statement

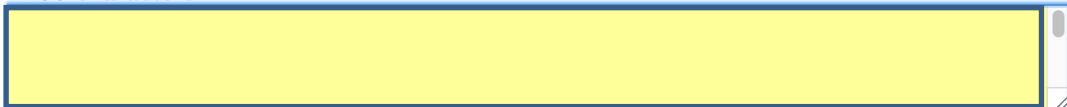
Describe the type(s) of cloud computing service(s) you wish to obtain (e.g., PaaS, SaaS, IaaS, DaaS) and how you plan to use it (them) to carry out the work described in your Research Use Statement (e.g., datasets to be included, process for data transfer, analysis, and storage, and tools and/or software to be used). Also describe the role of any collaborators. Please limit your statement to 2000 characters.

- “Non-technical summary” – Paste the **Non-Technical Summary** text in the box:

“The goal of the NHLBI Big Data Analysis Challenge program is to identify new open-source adult heart failure disease models. Though known to be a multi-organ, systemic syndrome with many related but seemingly different symptoms, adult heart failure is often simply categorized by a single measurement – left ventricular ejection fraction. Research indicates that physiological, social, behavioral, environmental, and genetic features may all have considerable influence in heart failure. Thus, the Challenge Solution will aim to develop an adult heart failure disease model that will incorporate many data types to support new research hypotheses in the field of heart failure research.”

***Non-technical summary** ⓘ

Please enter below a non-technical summary of your RUS suitable for understanding by the general public (written at a high school reading level or below). Please limit your non-technical summary to 1100 characters.



- “Choose your Signing Official (SO)” - You will see a list of Signing Officials for your institution. Check appropriate name (most Departments have a specific SO assigned to its members)
- “Applicant organization” – Add your institution’s name and address
- “Create Decryption Password” – create a password as instructed Click “Save and Continue” box at the bottom of the page
- If you selected cloud computing, you will be taken to the “Cloud Providers” tab.

“Cloud Providers” tab

- Add information pertaining to your cloud platform. Use the “Add Another” button if you plan to use more than one cloud environment. Fill in all of the information and then click “Save and Continue”.

“Collaborators” Tab

- Provide names and contact information for Internal Collaborators –i.e. colleagues at your institution who will share access to the data obtained via this application. Trainees, lab staff or postdocs need not be named individually, unless they are not under the direct supervision of the applicant.
- “Are you planning to collaborate with investigators from other institutions?” If your team includes members from other institutions, make sure that you have Unchecked “None”. Then you will see a box for adding the names and contact information for External collaborators. Enter the names and contact information for each of the team members from other institutions. If you do not have any external collaborators, you can leave “None” checked and proceed to “Save and Continue”.
- Click “Save and Continue” box at the bottom of the page

“IT Director” tab

- Enter name, position/title, organization, address, email and phone for an institutional-level IT director at your institution (e.g. CIO, CISSO).
- Click “Save and Continue” box at the bottom of the page

“Choose Datasets” tab

- This is the same page that came up earlier. You can add more datasets now if needed.

“Confirm Datasets” tab

- Check the list displayed to be sure it contains each of the accessions you need. If you missed any, you can click the “Back” button to return to “Choose Datasets”.
- Then click “Remove Selected and Continue”. This will **NOT** remove any of the accessions in your list unless you have selected “remove” in the drop-down menu for a given accession.

“Review DUC” tab

- Read the “Data Use Certification Agreement” for each accession. All data uses through this application will need to follow the terms in these documents.

“Review DUL” tab

- For each requested data set, click the box “I understand and agree...”, indicating your agreement, based on the documents in the previous section and the stated Data Use Limitations.

Consent Group	Data Use Limitations	Participants	DAR Status
NHLBI WGS: Gene-Environment, Admixture and Latino Asthmatics (GALAII) Study (phs000920.v1.p1)			
Exchange Area (phs000920.v1.p1.c999), NHLBI	Use by NHLBI WGS study investigators only There is one consent group for this study: DS-LD, Disease-Specific (Lung Disease) Informed consent restrict the use of data analysis related to lung diseases including asthma/allergies (immunologic disease), asthma related traits(e.g., obesity), drug response, genetic ancestry to adjust for differences between cases and controls and to identify new genes related to clinical phenotypes. <input checked="" type="checkbox"/> I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	0	

- Click “I understand and agree to the terms...”

“Review Applications” tab

- Click on the pdf icon labeled as “Review Complete Application” and review it. Check the two “I agree” boxes to provide the required certifications and assurances.
- Click “Submit Application to Signing Official” button.

Following status

- You will receive automated emails indicating status of application approval. You can also check status by clicking the “My Requests” tab after logging in with your eRA Commons ID
- Do NOT email DAC members with notification that you have submitted an application. They will see it as it comes through the dbGaP system.